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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/781,984

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Evgenia Mandrusov

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EXAMINER

SMITH, RUTH S

ART UNIT

PAPER NUMBER

3737

MAIL DATE

DELIVERY MODE

12/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/781,984	Applicant(s) MANDRUSOV ET AL.	
	Examiner Ruth S. Smith	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-14,23 and 25-43 is/are pending in the application.
- 4a) Of the above claim(s) 23,25-31 and 33-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-14,32 and 38-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Applicant's election without traverse of the invention of Group I in the reply filed on 4/17/09 is acknowledged. It should be noted that while claim 32 has a status identifier of "withdrawn", it depends from claim 1 and is part of the invention of Group I and will be examined on its merits.

Claims 23,25-31,33-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/17/09.

Specification

The disclosure is objected to because of the following informalities: applicant should update the status of the continuing data. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 43, "the carrier particles" lacks antecedent basis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1,3,5-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steward et al (6,554,801) in view of Kaplan et al (5,941,868). Steward et al disclose a method of promoting angiogenesis including positioning a delivery device in a blood vessel and ultrasonically imaging a thickness of the blood vessel with an imaging assembly positioned in a lumen of the delivery device, identifying a treatment site and then advancing the delivery device to the treatment site to deliver a treatment agent to the site. Steward et al fails to specifically disclose that the delivery device is advanced into a wall of the blood vessel beyond an external elastic lamina of the blood vessel. Kaplan et al disclose a method of promoting angiogenesis which includes delivering the treatment agent through the wall of the blood vessel beyond an external elastic lamina into the perivascular space surrounding the blood vessel. It would have been obvious to one skilled in the art to have modified Steward et al such that the agent is delivered to a site beyond the external elastic lamina of the blood vessel in view of the teachings of Kaplan et al as a known treatment site for promoting angiogenesis. The modified method of Steward et al would result in the treatment in areas as set forth in claims 5-8. Kaplan et al disclose the use of controlled release carriers for delivering the agent over a period of time. The use of such is a well known expedient in the art for drug delivery and would have therefore been obvious. With respect to claim 10, in the absence of any showing of criticality, the specific size of the carrier used would have been an obvious design choice of known equivalents in the art. With respect to claims 11-14, in the absence of any showing of unexpected results, the specific type of drug delivered

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would have been an obvious selection of known drugs depending upon the desired patient treatment.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Steward et al (6,554,801) in view of Kaplan et al (5,941,868) as applied to claim 10 above, and further in view of Segal (2002/0131974). Steward et al fails to disclose the use of an opsonin-inhibitor. The use of an opsonin-inhibitor is known in order to modulate the response to carriers put into a subject for treatment purposes. It would have been obvious to one skilled in the art to have further modified Steward et al such that the carrier includes an opsonin-inhibitor as is a well known expedient in the art of drug delivery.

Claims 12,13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steward et al (6,554,801) in view of Kaplan et al (5,941,868) as applied to claim 1 above, and further in view of Slepian et al (5,749,915). The use of materials such as polycaprolactone and polyurethane for treatments involving blood vessels are known as taught by Slepian et al and the use of such known materials would have been obvious. The materials can be incorporated into carriers for delivery such as nanoparticles or liposomes and can include other particles such as metallic particles. The materials can be inflammation inducing and are heated when introduced into the body. It would have been obvious to one skilled in the art to have further modified Steward et al such that materials such as polycaprolactone and polyurethane are used to further treat the vessels as is a well known expedient in the art.

Claims 4,32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steward et al (6,554,801) in view of Kaplan et al (5,941,868) as applied to claim 1 above, and further in view of Selmon et al (6,514,217). Steward et al disclose the use of IVUS to image the blood vessel but fails to disclose the use of optical imaging such as OCT. The use of both IVUS and OCT are well known in the art for imaging blood

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vessels as seen for example in Selmon et al. It would have been obvious to one skilled in the art to have further modified Seward et al such that the imaging modality used is OCT. Such a modification merely involves the substitution of one well known type of vascular imaging modality for another.

Claims 38-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan et al alone or in view of Slepian et al (5,749,915). Kaplan et al disclose a method for promoting angiogenesis which includes positioning a delivery device at a location in a blood vessel, advancing the device a distance into a wall of the blood vessel to a treatment site beyond an external elastic lamina of the blood vessel and introducing an agent to the treatment site. Kaplan et al disclose the use of controlled release carriers for delivering the agent over a period of time. Kaplan et al fails to disclose the use of an inflammation-inducing agent to stimulate angiogenesis. It should be noted that any material delivered into the wall of the blood vessel would cause some degree of inflammation. In the absence of any showing of criticality or unexpected results, the specific drug used to promote angiogenesis would have been an obvious selection of known drugs for achieving that purpose. Furthermore, the use of materials such as polycaprolactone and polyurethane for treatments involving blood vessels are known as taught by Slepian et al and the use of such known materials would have been obvious. The materials can be incorporated into carriers for delivery such as nanoparticles or liposomes and can include other particles such as metallic particles.

Response to Arguments

Applicant's arguments with respect to claims 1,3-14,32,38-43 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

RSS